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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,998	09/16/2003	Haishan Zeng	2055/41210 Case PA 5	3912

279 7590 12/13/2007

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EXAMINER	
CHAO, ELMER M	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,998	ZENG ET AL.	
	Examiner	Art Unit	
	Elmer Chao	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,20-25,30-48,53-58,63-70 and 73-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,20-25,30-48,53-58,63-70 and 73-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 11/27/2007.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/27/2007 has been entered.

Response to Arguments

3. Applicant's arguments with respect to claims 1 and 34 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1-15, 20-25, 30-32, 34-48, 53-58, and 63-65,** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulghum (U.S. 6,364,829 B1) in view of Freitag et al. (U.S. 6,061,591).

Regarding **claims 1-6, 11-15, 20-25, 30-32, 34-39, 44-48, 53-58, 63-65,** Fulghum '829 teaches a method for imaging and diagnosing a target comprising: illuminating the target with visible light and auto fluorescent light (abstract); a first step of assessing based on a white light imaging mode, comprising white light imaging (Fig. 4, Items 412, the step of determining valid pixels is considered an assessment); a second step of performing an additional assessment (Fig. 4, Item 426) to determine if the target is in a normal state or in an abnormal state; comparing a quantitative score to a benchmark score (Fig. 4, Items 432, 440, & 450; col. 9, lines 61-64; Fulghum '829 teaches a benchmark score for each pixel as the "predetermined value (typically one-half to one-third)," and a quantitative score as the "ratio image pixel value".); providing an action in the form of a visual alert based on prior information, and displaying said quantitative score and said benchmark score (col. 9, lines 64-67; col. 10, lines 1-14; Fig. 4, Fulghum '829 teaches the displaying of the scores on a LCD monitor as a false color map that compares the two scores and assigns a red (high probability of dysplasia), green (moderate probability of dysplasia), or gray (normal probability of dysplasia) for each pixel score comparison. These displayed colors act as visual alerts for the operator of the endoscope).

Fulghum '829 does not teach performing the second step as a simultaneous transparent background task. However, Freitag '591 teaches a first

white light assessing step and a second additional assessing step performed simultaneously (col. 1, lines 59-64) as a transparent background task wherein said second additional assessing step comprises fluorescence spectroscopy and fluorescence imaging (abstract; Freitag '591 teaches using a laser to stimulate fluorescence while simultaneously illuminating the site of interest with white light. The screen may display a normal white light endoscopic picture.), wherein a plug-in analyzer (fluorescence excitation-emission matrix spectroscopy probe) is used to analyze the fluorescent emissions (C3, L60-63; Note that the analyzer in the figures (Items 5, 15, and 43) are all "plugged into" the system). It would have been obvious to a person of ordinary skill at the time of the invention to modify Fulghum '829 to perform the additional assessment as a simultaneous transparent background task in order to increase the diagnosis possibilities of various cancer phenomena (col. 1, lines 59-64; col. 6, lines 37-39).

Fulghum '829 and Freitag '591 teach all of the limitations as discussed above. They do not explicitly teach changing a visual output mode by at least one of highlighting said suspect region. However, Fulghum '829 does teach highlighting dysplastic tissue with false color in a processed image of the tissue (col. 6, lines 15-21). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Fulghum '829 and Freitag '591 to include highlighting suspect regions of tissue on a white light image in order to allow a clinician to easily interpret the images (for motivation see col. 4, lines 54-57).

Regarding **claims 7, 8, 40, and 41**, Fulghum '829 and Freitag '591 teach all of the limitations as discussed above. They do not explicitly teach the method of manually switching between displays after the visual alert. However, Fulghum '829 does teach the use of a footswitch (Fig 2b, Item 206), which allows for the operator to switch between white light and fluorescence visualization (C3, L1-4). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Fulghum '829 and Freitag '591 to include using a footswitch to switch between white light and fluorescence visualization after the visual alert. Such a modification would be advantageous in allowing the operator to verify and observe signs of dysplasia from both white light and fluorescent images separately after the computer has identified high probability areas of dysplasia, and hence provide for a more accurate diagnosis.

Regarding **claims 9, 10, 42, and 43,** Fulghum '829 and Freitag '591 teach all of the limitations as discussed above. They do not explicitly teach the method of automatically switching between displays after the visual alert. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Fulghum '829 and Freitag '591 to include the method of automatically switching between displays after the visual alert using the computer provided by Fulghum '829 (Fig 3, Item 334) since its been held in *In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)* that merely providing an automatic means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. Furthermore, an automated switching mechanism, ideally provided by the computer in Fulghum '829 instead of a

manual switch would be a desirable alternative by relieving the operator from the burden of having to depress a switch.

6. **Claims 67-70 and 73-76** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulghum '829 in view of Freitag '591, further in view of Yang et al. (U.S. 2002/0049386 A1). Fulghum '829 and Freitag '591 teach the limitations as discussed above but fail to explicitly teach a third step of performing spectroscopy after said visual alert. However, in the same field of endeavor, Yang '386 teaches using spectroscopy to distinguish normal from diseased tissue and then further to separate diseased tissue into different stages of the tumor development (Para [003]). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to perform the additional step of spectroscopy after the visual alert in order to further separate diseased tissue into different stages of the tumor development (for motivation see Para [003]).

7. **Claims 33 and 66** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulghum '829 in view of Freitag '591, further in view of Strommer et al. (US 2002/0049375). Fulghum '829 and Freitag '591 teach the limitations as discussed above. They do not explicitly teach a method of using an endoscopy positioning system. However, Strommer '375 teaches the use of a medical positioning system to navigate an endoscope (abstract; Para [0026], Strommer '591 describes the use of an endoscope as the surgical tool).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use an endoscopy positioning system. Such a modification would be advantageous in its own right because it would allow the operator to know the position of the endoscope to better locate any abnormities in the tissue.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC
12/9/2007